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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/716,169	12/17/1996	STEPHEN M. ANDERTON	961125	5487

7590

11/25/2002

WEBB ZIESENHEIM BRUENING LOGSDON  
ORKIN & HANSON  
700 KOPPERS BUILDING  
436 SEVENTH AVENUE  
PITTSBURGH, PA 152191818

EXAMINER

NOLAN, PATRICK J

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 11/25/2002

56

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**Application No.  
**08/716,169**Applicant(s)  
**Anderton et al.**Examiner  
**Patrick J. Nolan**Art Unit  
**1644**

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

Extensions of time may be available under the provisions of 37 CFR 1.136 (e). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.

If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.

If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.

Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on Sep 13, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 24-30 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 24-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

**Part III DETAILED ACTION**

1. This application is a 371 of PCT/NL95/00108.
2. Claims 24-30 are pending.
3. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9-23-02 has been entered.
4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 24-30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for using the recited peptides for protecting against experimentally induced adjuvant arthritis or atherosclerosis, does not reasonably provide enablement for treating any inflammatory disease, particularly autoimmune diseases. The specification does not enable any person skilled in the art to which it pertains, or with which it is most clearly connected, to use the invention commensurate in scope with these claims.

Applicant's arguments filed 9-23-02 have been fully considered but are not found persuasive.

Applicant argues the prior art does not disclose it would be unpredictable to use an APL according to the specific changes set forth in claim 29, therefore in light of the specification's teachings and the declaration filed the full breadth of the claimed invention is enabled.

However, upon a review of Applicant's own publications, it is clear the ability of one of skill in the art to extrapolate limited animal model data to human treatment is unpredictable.


Anderton et al., one of the Applicant's, newly cited, in reviewing the usefulness of APL therapy in humans concluded against the use of APL's in human autoimmune disorders, even though animal data was very promising, and that such an approach in an outbred

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human population might aggravate rather than reduce pathology (page 370, 1st paragraph 2nd column). In addition, Wendling et al., of which two of the authors are co-inventors, newly cited, clearly teaches that route of administration, nasal worked while parenteral did not, appears to be critical in treating autoimmune diseases with conserved mycobacterial heat shock proteins. Wendling et al., reasons that the stimulation of IL-10 production for bystander suppression appears to be critical for tolerance induction. It is recently known that nasal administration favors IL-10 production while other routes (parenteral) do not. However, such a fine tuning of administration was not disclosed by the instant Application, but appears critical to the enablement of the claimed invention.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is (703) 305-1987. The examiner can normally be reached on Monday through Friday from 8:30 am to 4:30 pm.

7. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (703) 305-3973. The FAX number for our group, 1644, is (703) 305-7939. Any inquiry of a general nature relating to the status of this application or proceeding should be directed to the Group receptionist, whose telephone number is (703) 308-0196.



Patrick J. Nolan, Ph.D.  
Patent Examiner, Group 1640  
November 23, 2002